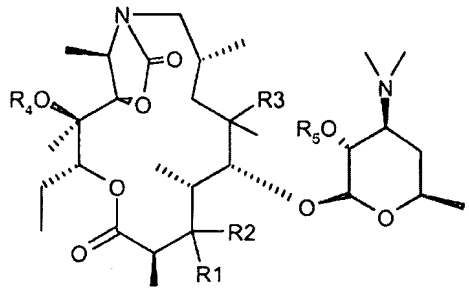
AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims

1. (Currently amended) ~~Novel 3-decladinosyl derivatives of 9-deoxo-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate~~ A compound of ~~the general~~ formula **(I),**

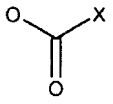


(I)

~~their pharmaceutically acceptable addition salts with inorganic or organic acids and their hydrates,~~

wherein

R_1 individually ~~stands for~~ represents hydrogen, hydroxyl or a group of the formula **(II),**



(II)

wherein

X individually ~~stands for~~ represents C_1-C_6alkyl group, C_2-C_6alkenyl group; or X individually ~~stands for~~ represents C_1-C_6alkyl group with at least one incorporated O, S or N atom or X individually ~~stands for~~ represents $(CH_2)_n$-Ar or X individually ~~stands for~~ represents $(CH_2)_n$-heterocycloalkyl, wherein $(CH_2)_n$ individually ~~stands for~~ represents alkyl, wherein n is 1-10, with or without incorporated atom O, S or N, wherein Ar individually ~~stands for~~ represents 5-10-membered monocyclic or ~~bycyclic~~ bicyclic aromatic ring with 0-3 ~~atom~~ O, S or N atoms, unsubstituted or substituted with 1-3 ~~group~~ groups, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkyl, and heterocycloalkyl ~~stands for~~ represents unaromatic, partially or completely saturated 3-10-membered monocyclic or bicyclic ring system, ~~which includes 3-8-membered monocyclic or bicyclic ring, which includes~~ or a 6-membered aromatic or heteroaromatic ring connected with a unaromatic ring with or without incorporated O, S or N atom, unsubstituted or substituted with 1-4 ~~group~~, groups which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkil, -C(O)-, COOH

or

R_1 together with R_2 ~~stands for~~ represents ketone,

R_2 individually ~~stands for~~ represents hydrogen or together with R_1 ~~stands for~~ represents ketone or together with R_3 ~~stands for~~ forms an ether bond,

R_3 individually ~~stands for~~ represents hydroxyl, a group of the formula –OX or together with R_2 ~~stands for~~ forms an ether bond,

R_4 individually ~~stands for~~ represents hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group, and

R_5 individually ~~stands for~~ represents hydrogen or hydroxyl protected group,

or a pharmaceutically acceptable addition salt or hydrate thereof.

2. (Currently amended) A Compound according to claim 1, characterised in that R_1 ~~stands for~~ represents hydroxyl, R_2 and R_5 are mutually the same and ~~stands for~~ represents hydrogen, R_3 individually ~~stands for~~ represents hydroxyl or for group of the formula –OX, wherein X individually ~~stands for~~ represents C_1-C_6alkyl group, C_2-C_6alkenyl group or X individually ~~stands for~~ represents C_1-C_6alkyl

group with at least one incorporated O, S or N atom or X individually ~~stands for~~ represents $(CH_2)_n$-Ar or X individually ~~stands for~~ represents $(CH_2)_n$-heterocycloalkyl, wherein $(CH_2)_n$ individually ~~stands for~~ represents alkyl, wherein n is 1-10, with or without incorporated ~~atom~~ O, S or N atom, wherein Ar individually ~~stands for~~ represents 5-10-membered monocyclic or ~~bycyclic~~ bicyclic aromatic ring with 0-3 ~~atom~~ O, S or N atoms, unsubstituted or substituted with 1-3 ~~group~~ groups, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkyl, and heterocycloalkyl ~~stands for~~ represents unaromatic, partially or completely saturated 3-10-membered monocyclic or bicyclic ring system, ~~which includes 3-8-membered monocyclic or bicyclic ring~~, ~~which includes~~ or a 6-membered aromatic or heteroaromatic ring connected with a unaromatic ring with or without incorporated O, S or N atom, unsubstituted or substituted with 1-4 ~~group~~ groups, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkil, -C(O)-, COOH and R_4 individually stands for hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group.

3. (Currently amended) A Compound according to claim 2, characterised in that R_4 ~~stands for~~ represents hydrogen.

4. (Currently amended) A Compound according to claim 2, characterised in that R_4 ~~stands for~~ represents methyl group.

5. (Currently amended) A Compound according to claim 2, characterised in that R_4 ~~stands for~~ represents ethyl group.

6. (Currently amended) A Compound according to claim 1, characterised in that R_1 ~~stands for~~ represents group of the formula **(II)**, wherein X individually ~~stands for~~ represents C_1-C_6alkyl group, C_2-C_6alkenyl group or X individually ~~stands for~~ represents C_1-C_6alkyl group with at least one incorporated O, S or N atom or X individually ~~stands for~~ represents $(CH_2)_n$-Ar or X individually ~~stands for~~ represents $(CH_2)_n$-heterocycloalkyl, wherein $(CH_2)_n$ individually ~~stands for~~ represents alkyl, wherein n is 1-10, with or without incorporated atom O, S or N, wherein Ar individually ~~stands for~~ represents 5-10-membered monocyclic or bycyclic aromatic ring with 0-3 atom O, S or N, unsubstituted or substituted with 1-3 group, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkyl, and

heterocycloalkyl ~~stands for~~ represents unaromatic, partially or completely saturated 3-10-membered monocyclic or bicyclic ring system, ~~which includes 3-8-membered monocyclic or bicyclic ring, which includes~~ or a 6-membered aromatic or heteroaromatic ring connected with a unaromatic ring with or without incorporated O, S or N atom, unsubstituted or substituted with 1-4 group, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3~~alkil~~ alkyl, -C(O)-, COOH, R_2 and R_5 are mutually the same and ~~stands for~~ represent hydrogen, R_3 individually ~~stands for~~ represents hydroxyl or ~~for~~ group of the formula –OX and R_4 individually ~~stands for~~ represents hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group.

7. Cancelled
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26. Cancelled
27. (Currently amended) A Compound according to claim 1, characterised in that R_1 and R_5 are mutually the same and ~~stands for~~ represent hydrogen, R_2 together

with R_3 ~~stands for~~ forms an ether bond and R_4 individually stands for hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group.

28. Cancelled

29. Cancelled

30. Cancelled

31. Cancelled

32. Cancelled

33. Cancelled

34. (Currently amended) A Compound according to claim 1, characterised in that R_1 ~~stands for~~ represents hydroxyl, R_2 together with R_3 ~~stands for~~ forms an ether bond, R_5 ~~stands for~~ represents hydrogen and R_4 individually stands for hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group.

35. Cancelled

36. Cancelled

37. Cancelled

38. Cancelled

39. Cancelled

40. Cancelled

41. (Currently amended) A Compound according to claim 1, characterised in that R_1 together with R_2 stands for keto, R_3 ~~stands for~~ represents group of the formula -OX, R_5 ~~stands for~~ represents hydrogen and R_4 individually ~~stands for~~ represents hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group.

42. Cancelled

43. Cancelled

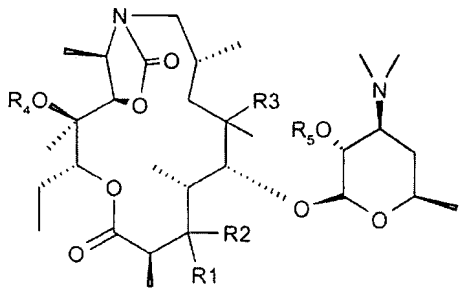
44. Cancelled

45. Cancelled

46. Cancelled

47. Cancelled

48. (Currently amended) A ~~proces~~ process for preparation of a compound~~s~~ of ~~the~~ formula **(I)**,

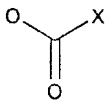


(I)

~~their pharmaceutically acceptable addition salts with inorganic or organic acids and their hydrates,~~

wherein

R_1 individually ~~stands for~~ represents hydrogen, hydroxyl or a group of the formula **(II)**,



(II)

wherein

X individually ~~stands for~~ represents C_1-C_6alkyl group, C_2-C_6alkenyl group or X individually ~~stands for~~ represents C_1-C_6alkyl group with at least one incorporated O, S or N atom or X individually ~~stands for~~ represents $(CH_2)_n$-Ar or X individually ~~stands for~~ represents $(CH_2)_n$-heterocycloalkyl, wherein $(CH_2)_n$ individually ~~stands for~~ represents alkyl, wherein n is 1-10, with or without incorporated ~~atom~~ O, S or N atom, wherein Ar individually ~~stands for~~ represents 5-10-membered monocyclic or ~~bycyclic~~ bicyclic aromatic ring with 0-3 ~~atom~~ O, S or N atoms, unsubstituted or substituted with 1-3 ~~group~~ groups, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN,

SO_2NH_2, C_1-C_3alkyl, and heterocycloalkyl ~~stands for~~ represents unaromatic, partially or completely saturated 3-10-membered monocyclic or bicyclic ring system, ~~which includes 3-8-membered monocyclic or bicyclic ring, which includes~~ or a 6-membered aromatic or heteroaromatic ring connected with a unaromatic ring with or without incorporated O, S or N atom, unsubstituted or substituted with 1-4 ~~group~~ groups, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3~~alkil~~ alkyl, -C(O)-, COOH

or

R_1 together with R_2 stands for represents ketone,

R_2 individually stands for hydrogen or together with R_1 ~~stands for~~ represents ketone or together with R_3 ~~stands for~~ forms an ether bond,

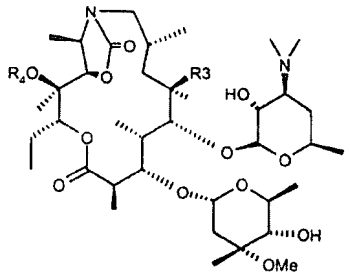
R_3 individually ~~stands for~~ represents hydroxyl, a group of the formula –OX or together with R_2 ~~stands for~~ forms an ether bond,

R_4 individually ~~stands for~~ represents hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group, and

R_5 individually ~~stands for~~ represents hydrogen or hydroxyl protected group, or a pharmaceutically acceptable salts or hydrate thereof,

characterised in that

a) ~~starting compounds~~ a compound of ~~the~~ formula **3** ~~(scheme 1.)~~



3

~~are~~ is subjected to hydrolysis with strong acids~~, preferably with 0,25-1,5 *N* hydrochloric acid,~~ in a mixture of water and lower alcohols~~, preferably methanol, ethanol or isopropanol,~~ over 10-30 hours at room temperature yielding a

compounds of ~~general~~ formula **(I)**, wherein R_1 ~~stands for~~ represents hydroxyl, R_2 and R_5 are mutually the same and ~~stands for~~ represents hydrogen, R_3 individually ~~stands for~~ represents hydroxyl or ~~for~~ a group of the formula –OX, wherein X individually ~~stands for~~ represents C_1-C_6alkyl group, C_2-C_6alkenyl group or X individually ~~stands for~~ represents C_1-C_6alkyl group with at least one incorporated O, S or N atom or X individually ~~stands for~~ represents $(CH_2)_n$-Ar or X individually ~~stands for~~ represents $(CH_2)_n$-heterocycloalkyl, wherein $(CH_2)_n$ individually ~~stands for~~ represents alkyl, wherein n is 1-10, with or without incorporated atom O, S or N, wherein Ar individually ~~stands for~~ represents 5-10-membered monocyclic or ~~bycyclic~~ bicyclic aromatic ring with 0-3 atom O, S or N, unsubstituted or substituted with 1-3 group, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkyl, and heterocycloalkyl ~~stands for~~ represents unaromatic, partially or completely saturated 3-10-membered monocyclic or bicyclic ring system, ~~which includes 3-8-membered monocyclic or bicyclic ring, which includes~~ or a 6-membered aromatic or heteroaromatic ring connected with a unaromatic ring with or without incorporated O, S or N atom, unsubstituted or substituted with 1-4 group, which are selected independently from halogen, OH, OMe, NO_2, NH_2, amino-C_1-C_3alkyl or amino-C_1-C_3dialkyl, CN, SO_2NH_2, C_1-C_3alkil, -C(O)-, COOH and R_4 individually ~~stands for~~ represents hydrogen, C_1-C_4alkyl group or C_2-C_4alkenyl group,

which ~~are~~ is then subjected to

b) a selective acylation of the hydroxyl group at 2'-position~~, preferably with acetyl group by acylation, preferably~~ with a chlorides or anhydrides of a carboxylic acids with up to 4 carbon atoms~~, preferably with acetic acid anhydrides~~, in the presence of inorganic or organic base, in a reaction–inert solvent at a temperature from 0-30°C, yielding a 2'-O-acyl derivatives of ~~the general~~ formula **(I)**, wherein R_1 ~~stands for~~ represents hydroxyl, R_2 ~~stands for~~ represents hydrogen, R_3 individually ~~stands for~~ represents hydroxyl or group of the formula –OX, R_5 ~~stands for~~ represents acetyl group and R_4 and X have the meanings defined in a)

which ~~are than opttionaly~~ is then optionally subjected to

c1) a reaction with mixed anhydrides of carboxylic acids of the formula Y-COO-R', wherein Y ~~stands for~~ represents hydrogen or ~~stands for~~ represents group X~~, which is defined above,~~ wherein X is as defined in step a), wherein R' ~~stands for~~ represents ~~the~~ a group ~~which is usually used for preparation of mixed anhydrides as~~ selected from pivaloyl-, p-toluensulphonyl-, isobutoxycarbonyl-, etoxycarbonyl- ~~or~~ and isopropoxycarbonyl-group, in the presence of inorganic or organic base, in a reaction–inert solvent, ~~preferably methylene chloride~~ at a temperature from 0-30°C for 3-100 hours yielding a compounds of ~~the general~~ formula (I), wherein R_1 ~~stands for~~ represents a ~~the goup~~ group of ~~the general~~ formula **(II)** as defined above, R_2 ~~stands for~~ represents hydrogen, R_3 individually ~~stands for~~ represents hydroxyl or the group of the formula –OX, wherein R_5 ~~stands for~~ represents acetyl, and substituents R_4 and X ~~have the above meanings~~ are as defined in step a), which is then ~~Formed compounds are subsequently~~ subjected to deprotection with a lower alcohol~~s, preferably in methanol,~~ at a temperature from room temperature to the reflux temperature of the solvent, yielding a compound of ~~the~~ formula **(I)**, wherein R_5 ~~stands for~~ represents hydrogen and R_3, R_4 and X have the ~~above~~ meanings as defined in c1);

or ~~they are opttionaly subjected,~~

c2) when R_3 ~~stands for~~ represents group of formula OX and the remaining ~~supstituents~~ substituents have the meanings defined in b), a compound from step b) is subjected to oxidation of the hydroxyl group in the C-3 position of an aglycone ring ~~according to a modified Moffat-Pfitzner process~~ with N,N-dimethylaminopropyl-3-ethyl-carbodiimide in the presence of dimethylsulfoxide and pyridinium trifluoracetate as a catalyst in a inert organic solvent~~, preferably in methylene chloride,~~ at a temperature from 10 °C to room temperature, yielding a compounds of ~~the~~ general formula **(I)**, wherein R_1 together with R_2 ~~stands for~~ represents ketone, R_3 ~~stands for~~ represents ~~the~~ a group of the formula –OX, R_5 ~~stands for~~ represents acetyl and ~~supstituents~~ substituents R_4 and X have the

above meanings defined in step a), which is then ~~Formed compounds are subsequently~~ subjected to deprotection with a lower alcohols~~, preferably in methanol,~~ at a temperature from room temperature to the reflux temperature of the solvent, yielding a compound of ~~the~~ general formula **(I)**, wherein R_1 and R_2 together represent ketone, wherein R_5 ~~stands for~~ represents hydrogen and all other ~~supstituents~~ substituents have the ~~above~~ meanings as defined in c2);

or ~~they are opttionaly subjected,~~

c3) when R_3 ~~stands for~~ represents hydroxyl and the remaining ~~supstituents~~ substituents have the meanings defined in step b), the compound from step b) is subjected to oxidation described in step c) to obtain a 3,6-hemiketal compounds of ~~the~~ general formula **(I)** ~~from the step c2), where compounds with 3,6-hemiketal structure given by general formula (I),~~ wherein R_1 ~~stands for~~ represents hydroxyl, R_2 together with R_3 ~~stands for~~ forms an ether bond, R_5 ~~stands for~~ represents acetyl and R_4 has the above meanings~~.~~, which is then ~~Formed compounds are subsequently~~ subjected to deprotection with a lower alcohols~~, preferably in methanol,~~ at a temperature from room temperature to the reflux temperature of the solvent, yielding a compound of ~~the general~~ formula **(I)**, wherein R_5 ~~stands for~~ represents hydrogen and all other ~~supstituents~~ substituents have the ~~above~~ meanings defined in step c3);

or ~~they are opttionaly subjected,~~

c4) when R_3 ~~stands for~~ represents hydroxyl and the remaining ~~supstituents~~ substituents have the meanings defined in step b), ~~to adequate reagents for dehydratation preferably methylsulfonyl anhydride to transform~~ hydroxyl group on the C-3 position ~~3~~ of a compound from step b) is transformed to a ~~in~~ good leaving group, using methylsulfonylchloride, in an inert organic solvent~~, preferably in pyridine,~~ at a temperature from room temperature to the reflux temperature of the solvent for 10-50 hours~~.~~ , then to elimination using ~~Formed intermediate is subsequently subjected to reaction of elimination with adequate reagens preferably~~ sodium hydride, in a inert organic solvent~~, preferably in~~

~~tetrahydrofuran,~~ at a temperature from 10 °C to room temperature, yielding a 3,6-cyclic ether compound of ~~the general~~ formula **(I)**, wherein R_1 ~~stands for~~ represents hydrogen, R_2 together with R_3 ~~stands for~~ represents ether, R_5 ~~stands for~~ represents acetyl and R_4 has the above meanings~~.~~ , which is then ~~Formed compounds are subsequently~~ subjected to deprotection with a lower alcohol~~s~~, ~~preferably in methanol,~~ at a temperature from room temperature to the reflux temperature of the solvent, yielding a compound of ~~the general~~ formula **(I)**, wherein R_5 stands for hydrogen and all other ~~supstituents~~ substituents have the ~~above~~ meanings as defined in C4).

49. (New) A compound selected from the group consisting of:
3-Decladinosyl-3-oxy-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-oxy-12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-oxy-12-O-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate; and
2'-O-Acetyl-3-decladinosyl-3-oxy-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;

50. (New) A compound selected from the group consisting of:
3-Decladinosyl-3-O-(4-nitrophenyl)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-aminophenyl)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-fluorophenyl)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-methoxyphenyl)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(benzyl)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(pyridyltio)acyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate,

3-Decladinosyl-3-O-acetyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-nitrophenyl)acyl-12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-aminophenyl)acyl-12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3-O-(4-nitrophenyl)acyl-12-O-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate; and
3-Decladinosyl-3-O-(4-aminophenyl)acyl-12-O-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate.

51. (New) A compound selected from the group consisting of:
3-Decladinosyl-3,6-cyclic ether 9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3,6-cyclic ether 12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate; and
3-Decladinosyl-3,6-cyclic ether 12-O-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate.

52. (New) A compound according selected from the group consisting of:
3-Decladinosyl-3,6-hemiketal 9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
3-Decladinosyl-3,6-hemiketal 12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate; and
3-Decladinosyl-3,6-hemiketal 12-O-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate.

53. (New) A compound according selected from the group consisting of:
2'-O-Acetyl-3-decladinosyl-3-oxy-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;
2'-O-Acetyl-3-decladinosyl-3-oxy-12-O-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerithromycin A 9a,11-cyclic carbamate;

2'-*O*-~~Acetil~~ Acetyl-3-decladinosyl-3-oxy-12-*O*-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate.

2'-*O*-Acetyl-3-decladinosyl-3,6-hemiketal 9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate;

2'-*O*-Acetyl-3-decladinosyl-3,6-hemiketal 12-*O*-methyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate; and

2'-*O*-Acetyl-3-decladinosyl-3,6-hemiketal 12-*O*-ethyl-9-deoxo-9-dihydro-9a-aza-9a-homoerythromycin A 9a,11-cyclic carbamate.